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**REMARKS**

Claims 1 and 9-12 were previously cancelled.

Claim 5 was amended to define the size of the encapsulated alcohol in view of the disclosure of Sorkin (US Pat. No. 5,952,393). Support for the amendment can be found throughout the specification at, for example, page 7, lines 16-22.

It is submitted that no new matter has been added by the above amendments.

**Anticipation Rejection**

Claims 5-8 were rejected under 35 USC §102(a) as anticipated by Sorkin, US Patent No. 5,952,393 ("Sorkin"). (Paper No. 5 at 2.)

For the reasons set forth below, the rejection, respectfully is traversed.

Sorkin discloses

The present invention provides a composition for reducing serum cholesterol levels in humans and animals. The composition comprises from about 5% to about 75% by weight of phytosterol, and from about 1% to about 60% by weight of policosanol. The composition further comprises from 0% to about 65% by weight of pharmaceutically acceptable formulation aids, such as diluents, stabilizers, binders, buffers, lubricants, coating agents, preservatives, emulsifiers and suspension agents.

In a preferred embodiment, the composition comprises from about 10% to about 60% by weight of phytosterol, and from about 3% to about 46% by weight of policosanol. In the most preferred embodiment of the invention, the composition comprises about 3.2:1 parts by weight of phytosterol and policosanol.

(col. 2, lns. 7-21);

As noted previously, policosanol is a mixture of high-molecular weight aliphatic alcohols. These alcohols occur naturally in wax form and are characterized by fatty alcohol chains ranging from 20 to 39 carbon atoms in length. The major component of policosanol are the aliphatic alcohols octacosanol and triacontanol. Policosanol is isolated from a number of different plant sources, including sugar cane wax and rice bran wax. The policosanol used in the preferred

(col. 2, lns. 26-33);

Phytosterols are also mixtures of long-chained aliphatic alcohols in a wax form. They are naturally occurring in many common vegetable food products. The particular phytosterol used in the preferred embodiment of the invention is derived from vegetable oil and has the formulation set forth in Table 2. This material is sold under the trademark "CHOLESTATIN" and is available from Traco Labs, Inc. Again, however, it should be understood that the invention is not limited to this particular phytosterol product, and that any number of other commonly available phytosterols can be used.

(col. 2, lns. 57-67); and

## EXAMPLE 1

Tablet Formula:

ingredient	amt/cap	function
"CHOLESTATIN" (Min. 88% phytosterols)	250 mg	active
"Rice Bran Wax" (23-33% policosanols)	250 mg	active
Calcium phosphate	261.7 mg	base
Cellulose	49.4 mg	tablet coating agent
Stearic acid	23.8 mg	lubricant
Magnesium stearate	6.8 mg	lubricant
Silicon dioxide	9.4 mg	diluent

(col. 3, lns. 29-41).

In making the rejection, the Examiner asserted that "Sorkin teaches a composition for reducing serum cholesterol comprising a mixture of long chain aliphatic alcohols, e.g., policosanols and phytosterol; and binders, coating agents, diluents emulsifiers, suspension agents, or stabilizers." (Paper No. 5 at 2.) The Examiner further asserted that "[t]he mixture of policosanols and phytosterol can be incorporated into a soft gelatin capsule or coated with a tablet coating agent." (*Id.* at 2.) The Examiner has contended that "Example 1 also discloses the with ration of the long chain aliphatic alcohol to excipients." (*Id.*)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

In a §102(a) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to *identify wherein each and every facet* of the claimed invention is disclosed in the applied reference. The Examiner is required to point to the disclosure in the reference "*by page and line*" upon which the claim allegedly reads.

At the outset, the Examiner's assertion that "Example 1 also discloses the weight ratio of the long chain aliphatic alcohol to the excipients" appears not to support the instant rejection. First, the claimed invention is not directed to, among other things, "excipients" which appears not to have a factual foundation to include "a food grade acceptable material selected from the group consisting of coating polymers, waxes and plasticizers" as currently required by the claims. That was Examiner's burden to carry. Because the Examiner failed to meet that minimum burden, the rejection is improper and should be withdrawn.

Nonetheless, the claims have been amended to recite a particular size for the encapsulated alcohol in the present invention. It is not seen where Sorkin discloses the claimed composition having the encapsulated alcohol as presently claimed. For this additional reason, the rejection is improper and should be withdrawn.

**Obviousness Rejection**

Claims 2-6 were rejected under 35 USC §103(a) as being unpatentable over Mothes, US Pat. No. 5,961,707. (Paper No. 5 at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Mothes discloses “granules having a relatively high content of ethanol (below ‘alcohol’) and a process for the preparation of alcohol containing granules by fluidized-bed spray granulation.” (Col. 1, Ins. 6-9.) The granules were disclosed as having particle diameters of 0.1 to 2 mm. (Col. 3, Ins. 34-36.) Coating materials for the granules were disclosed as being simple and modified starches, gelatin, cellulose, and cellulose derivatives, lactose, fats, waxes and the like. (Col. 3, Ins. 45-49.) In addition, Mothes discloses that the alcohol-containing granules can serve as additive for a multiplicity of pulverulent foods (for example dry soups, sauces, desserts, beverages etc.). (Col. 3, Ins. 57-60.)

In making the rejection, the Examiner contended that Mothes “teaches alcohol-containing granules coated with waxes, cellulose, gelatin, lactose, or starches. (Paper No. 5 at 3.) The Examiner also asserted that “[t]he alcohol-containing granules can be incorporated into dry soups, sauces, desserts, and beverages.” The Examiner then asserted that “[a]lthough Mothes is silent as to the teaching of the intended use being claimed.... the intended us[e] is inherent since Mothes obtains the same result from the use of encapsulated alcohol as additives useful in dry soups, sauces, desserts, and beverages.” The Examiner also admitted that “Mothes is silent as to the teaching of long-chain alcohol.” (*Id.*)

The Examiner concluded that “it would have been obvious for one of ordinary skill in this art to use any alcohol, which will include long-chain alcohol, fatty alcohol, or aliphatic alcohol.” The Examiner reasoned that “[t]he expected result would be low dust content and free-flowing encapsulated alcohol granules.” (*Id.*)

Obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness *must* be based upon facts, “cold hard facts.” When a conclusion of obviousness is not based upon facts, it cannot stand.

Mothes defined ethanol as being the alcohol that was the subject of the document. (Col. 1, lns. 6-9.) As admitted by the Examiner, Mothes does not disclose the claimed long chain alcohol. **The Examiner did not provide any evidence** that would provide one of ordinary skill in the art with any expectation of success. **The record contains no evidence of the equivalence between ethanol and the long chain alcohol affirmatively required in the claims of the captioned application.**

The Examiner asserted that because Mothes allegedly discloses, in addition to alcohol and starch, natural and nature-identical flavorings can also be added to the granules “such language does suggest one of ordinary skill in the art to, by routine experimentation select a long chain (natural and nature-identical) compound that can also be added to the granules. With all due respect, it is not seen what relevance a long chain compound that is natural or nature-identical has on establishing motivation for one of ordinary skill in the art to substitute ethanol, a volatile liquid, with a long chain alcohol of the present invention. The Examiner’s asserted motivation, it is submitted, falls short of equating ethanol with the long chain alcohol of the present invention. It is not seen where all alcohols have the same properties as the carbon chain increases in size.

The Examiner is asked to provide evidence pursuant to MPEP § 2144.03 and 37 CFR 1.104(d)(2) as to the interchangeability of ethanol and long chain alcohols of the present invention. Without such proof, it is submitted that the Examiner is merely undertaking impermissible hindsight reconstruction of the present invention. “Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. Because the rejection fails to satisfy the burden placed on the Examiner, the rejection is improper and should be removed.

Claims 2-8 and 13 were rejected under 35 USC §103(a) as being unpatentable over Mothes in view of Cain, WO 98/47385 (“Cain”). (Paper No. 5 at 3.)

For the reasons set forth below, the rejection respectfully is traversed.

Mothes’ disclosure set forth above is incorporated herein by reference.

Cain discloses fat-continuous emulsions of fat and water having a fat and an emulsifier system. (p. 2, lns. 26-29.) The emulsifier system was disclosed as being a blend of components, with emulsifying properties, having components (A), (B), and (C). (p. 2, lns. 29-32.) A was disclosed as being a partial glyceride, containing at least one fatty acid residue with at least 2 carbon atoms. B was disclosed as being a phospholipid. (p. 3, ln. 1.) C was disclosed as being a long chain alcohol having at least 20 carbon atoms in the carbon chain. (p. 3, lns. 2-3.) Cain disclosed that component (C) is present in a number of natural products such as wheatgerm-wax, carnauba-wax, rice bran wax and sugar cane wax. (p. 3, lns. 8-10.)

For the reasons set forth below, the rejection respectfully is traversed.

In making the rejection, the Examiner asserted that Mothes is relied upon for the reasons stated above. (Paper No. 5 at 4.) The Examiner acknowledged, however, that Mothes differs from the presently claimed invention in that “Mothes is silent as to the teaching of long-chain alcohol.”

To fill the acknowledged gap, the Examiner relied on Cain as “teach[ing] long-chain alcohol incorporated in food products, which can be used to provide simultaneously cholesterol-lowering properties.” (Paper no. 5 at 4.) The Examiner then concluded that “it would have been prima facie obvious for one of ordinary skill in the art to modify Mothes’ alcohol-encapsulated granules using the long chain alcohol in view of the teaching of Cain. The Examiner reasoned that this would result in a food product containing a long-chain alcohol encapsulated in a polymer and a healthier food product containing encapsulated long-chain alcohol useful in lower cholesterol.

The Examiner reasoned further that since “Mothes discloses that natural and nature-identical flavoring can also be added to the granules” and “Cain discloses long chain alcohols being present in a number of natural products” it would have been “prima facie obvious for one of ordinary skill in the art to modify Mothes’ alcohol-containing granules using the natural products in view of the teaching of Cain with the expectation of at least similar result, because the references teach the advantageous results of the use of encapsulated alcohol in food products.” (Paper No. 5 at 6-7.)

At the outset, the Examiner asserted that “the references teach the advantageous results of the use of encapsulated alcohol in food products.” With all due respect, it is not seen where in Cain such a disclosure is found. Further, it is submitted that the only advantage Mothes discloses is the addition of ethanol granules as additive for a multiplicity of pulverulent foods (for example dry soups, sauces, desserts, beverages etc).

Mothes defined ethanol as being the alcohol that was the subject of the document. (Col. 1, lns. 6-9.) As admitted by the Examiner, Mothes does not disclose the claimed long chain alcohol. Cain discloses long chain alcohols in a fat-continuous emulsion. The record contains no evidence of the equivalence between ethanol and the long chain alcohol affirmatively required in the claims of the captioned application. Nor has the Examiner provided any evidence that the disclosure of fat emulsions could be combined with a disclosure of ethanol-containing granules.

The Examiner's asserted motivation, it is submitted, falls short of equating ethanol with the long chain alcohol of the present invention. It is not seen where all alcohols have the same properties as the carbon chain increases in size.

The Examiner is asked to provide evidence pursuant to MPEP § 2144.03 and 37 CFR 1.104(d)(2) as to the interchangeability of ethanol and long chain alcohols of the present invention. Without such proof, it is submitted that the Examiner is merely undertaking impermissible hindsight reconstruction of the present invention. "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. Because the rejection fails to satisfy the burden placed on the Examiner, the rejection is improper and should be removed.

Because the rejection fails to satisfy the burden placed on the Examiner, the rejection is improper and should be withdrawn.

Claims 5-8 and 13 were rejected under 35 USC § 103(a) as being unpatentable over Sorkin (Paper No. 5 at 4.)

For the reasons set forth below, the rejection respectfully is traversed.

Sorkin's disclosure set forth above is incorporated herein by reference.

In making the rejection, the Examiner asserted that "Sorkin is relied upon for the reason stated above." The Examiner then concluded that "it would have been prima facie obvious for one of ordinary skill in this art to modify Sorkin's cholesterol lowering composition to obtain the claimed invention, because Sorkin teaches the advantageous results in the use of long chain aliphatic

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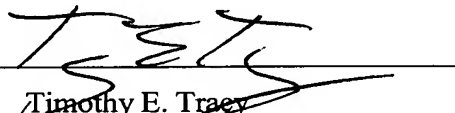
alcohols for the same purpose, e.g., for lowering serum cholesterol levels in human. (Paper No. 5 at 4.)

At the outset, the Examiner's assertion that "Example 1 also discloses the weight ratio of the long chain aliphatic alcohol to the excipients" appears not to support the instant rejection. First, the claimed invention is not directed to, among other things, "excipients" appears not to have a factual foundation to include "a food grade acceptable material selected from the group consisting of coating polymers, waxes and plasticizers" as currently required by the claims. That was Examiner's burden to carry. Because the Examiner failed to meet that minimum burden, the rejection is improper and should be withdrawn.

Nonetheless, the claims have been amended to recite a particular size for the encapsulated alcohol in the present invention. It is not seen where Sorkin discloses any motivation to make the claimed composition having the encapsulated alcohol as presently claimed. For this additional reason, the rejection is improper and should be withdrawn.

Accordingly, entry of the amendments and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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